FOOD MARKETING INSTITUTE

800 CONNECTICUT AVE., N.W.
WASHINGTON, D.C. 20006-2701
TELEPHONE: 202/452-8444
FAX: 202/429-4519
E-MAIL: FMI@FMI.ORG
WEBSITE: HTTP://WWW.FMI.ORG

May 28, 1999

Docket No. 99N-0438
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

99 MAY 28 P2:17

Re: Response to Request for Data and Information on Bare Hand Contact with Ready-to-Eat Foods (Docket No. 99N-0438)

Dear Sir or Madam,

The purpose of this letter is to respond to the Food and Drug Administration's (FDA's) Federal Register notice requesting data and information on the potential contamination of ready-to-eat foods by food preparation personnel. *See* 64 Fed. Reg. 15978 (April 2, 1999). Specifically, the Agency requested information on the risks of transmitting pathogens to ready-to-eat foods and the effectiveness of interventions, such as hand-washing and the use of disposable gloves, on preventing the spread of pathogens to food. The Agency also asked whether additional studies are need to fill existing knowledge gaps.

In response to FDA's request for information, enclosed please find a chapter on good hygiene practices for food-service personnel from a comprehensive manual prepared by the Hospitality Institute of Technology and Management. *See* Snyder, P., Chapter 24, "Personal Hygiene" in *HACCP-Based Safety and Quality Assured Retail Food Systems* (Feb. 1993). Furthermore, we have enclosed a copy of a two-part article that recently appeared in *Dairy, Food and Environmental Sanitation*. "Handwashing and Gloving for Food Protection Part I: Examination of the Evidence" provides a review of the published medical, microbiological and food industry literature on hand-washing and gloving practices. *See* 18 *Dairy, Food and Environmental Sanitation* 12 at 814 (Dec. 1998). Part II of the article, subtitled "Effectiveness," describes studies on the effectiveness of hand-washing and gloving for preventing the spread of pathogens that may be present on the hands of food-service personnel. *Id.* at 824.

These studies demonstrate that a thorough handwashing regimen is the most effective intervention for reducing the spread of pathogens to food. Gloves are not effective for preventing cross-contamination of food, unless proper personal hygiene practices are followed by the food service personnel. Gloving is not and should not be considered to be an effective substitute for proper hygienic practices. Indeed, an area in which further study should be conducted is whether the use of gloves actually discourages food service personnel from following the good personal hygiene practices that are essential to the prevention of cross-contamination of food, regardless of whether the food service employee is wearing gloves or relying on handwashing alone.

99N-0438

C 2

For your information, FMI is a non-profit association that conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 members and their subsidiaries. Our membership includes food retailers and wholesalers, as well as their customers, in the United States and around the world. FMI's domestic member companies operate approximately 21,000 retail food stores with a combined annual sales volume of $220 billion, which accounts for more than half of all grocery sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms, and independent supermarkets. Our international membership includes 200 members from 60 countries.

A. Background

FDA intends to prepare a summary of current information from the scientific literature and other sources that identifies and evaluates (1) the risks related to microbiological contamination of ready-to-eat food by food preparation workers and (2) the effectiveness of different interventions to prevent or minimize that risk. To ensure that FDA's "white paper" includes all available data, the Agency requested scientific data, studies, or other information related to the risk of transmitting pathogens from food preparation workers to ready-to-eat food, as well as scientific data or information on the effectiveness of interventions, such as hand washing with soap, hand-washing machines, the use of hand sanitizers, and the use of disposable gloves. In addition, the Agency requested comments on whether further studies are needed to fill existing knowledge gaps and, if so, what kinds of studies should be conducted.

B. Information Submitted

Part I of the "Handwashing and Gloving for Food Protection" article, provides a bibliography of 226 articles regarding the effectiveness of hand-washing and gloving interventions. *See* Fendler, *et al.*, "Handwashing and Gloving for Food Protection Part I: Examination of the Evidence" 18 *Dairy, Food and Environmental Sanitation* 12 at 814 (Dec. 1998) (hereinafter "Handwashing and Gloving Part I"). The articles are grouped into the following seven categories:

(1) General problems of food protection;
(2) Food Code and regulatory issues;
(3) Studies of the microflora of the skin;
(4) Efficacy of handwashing and gloving in microbial control;
(5) Micro-organisms and gloves;
(6) Methods of glove testing and the incidence and consequences of glove leakage; and
(7) Dermatological consequences of glove contact and skin occlusion.

See Handwashing and Gloving Part I at 814-815. We hope this bibliography will provide FDA with some useful articles on the subject of interest.

Part II of the article discusses two studies the authors conducted to assess the efficacy of gloves as an intervention measure and to compare the efficacy of gloving practices with hand-washing practices. *See* Fendler, *et al.*, "Handwashing and Gloving for Food Protection Part II: Effectiveness" 18 *Dairy, Food and Environmental Sanitation* 12 at 824 (Dec. 1998) (hereinafter "Handwashing and Gloving Part II"). In the latter study, gloved and ungloved subjects kneaded ground beef inoculated with *Escherichia coli* for three consecutive, one-hour periods. The subjects used the following six regimens:

(1) Bare hands/ No washing;
(2) Gloved hands/ No washing or glove changing;
(3) Bare hands/ Hourly washing;
(4) Bare hands/ Hourly washing and sanitizing;
(5) Gloved hands/ Hourly glove changes and no handwashing; and
(6) Gloved hands/ Hourly glove changes and handwashing between changes.

See Handwashing and Gloving Part II at 826. At the beginning and end of the study, microbial levels were measured on the subjects' hands and, where applicable, on the outside of their gloves. The lowest microbial values were observed on the hands of the subjects who did not use gloves but who washed their hands and applied a hand sanitizer on an hourly basis. *See* Handwashing and Gloving Part II at 828. The microbial values on the exterior surfaces of the gloves were higher than the values observed on the hands of those who handled the contaminated food with bare hands, but washed and sanitized their hands regularly. Thus, the use of gloves may cause more cross-contamination than a regimen of proper hygienic handwashing and and sanitizing practices.

The reasons why wearing gloves does not prevent cross-contamination of food are discussed in *HACCP-Based Safety and Quality Assured Retail Food Systems*. *See* Snyder, "Personal Hygiene" in *HACCP-Based Safety and Quality Assured Retail Food Systems* at 24-1, *et seq*. (Feb. 1998) (hereinafter "Personal Hygiene"). The primary issue concerns the hygiene and behavior practices of individuals who are wearing gloves. For example, if individuals do not wash their hands thoroughly before donning gloves, the food-contact surface of the gloves may well become contaminated with the very microorganisms from which the gloves are intended to form a barrier. *See* Personal Hygiene at 24-10.

Moreover, high levels of bacteria will multiply on the skin within the warm, moist glove environment. Therefore, hands must be thoroughly washed immediately after gloves are removed in order to reduce the high bacteria levels on the skin so that any surfaces or foods contacted after the gloves are removed will not become contaminated with high levels of bacteria. *See* Personal Hygiene at 24-9.

In addition, glove wearers often touch their faces, eyes, environmental surfaces, and contaminated raw food, inoculating the glove surfaces with mircoorganisms. Personnel wearing gloves may feel that their hands are clean, despite the fact that they have touched a number of different surfaces, and, therefore, may not recognize that dirt or substances have

accumulated on the gloves. *See* Personal Hygiene at 24-10. The gloves may, thus, provide a false sense of security that discourages food handlers from following personal hygiene and sanitation practices that are necessary, regardless of whether the food handler is wearing gloves. *See* Handwashing and Gloving Part II at 829.

The structure of gloves may also impact the potential for transmission of pathogens. For example, oils adhere to gloves and promote the subsequent adherence of microorganisms. *See* Personal Hygiene at 24-10. Moreover, as gloves are porous to viruses, such as Hepatitis A, that may be present on hands that have not been properly washed, viruses may transfer from hands through the gloves to contacted food. *See* Personal Hygiene at 24-10.

Although not directly related to microbial transmission, the potential for adverse allergic reactions from the natural rubber latex proteins in latex gloves should be considered. Not only are those who wear gloves at potential risk, but a report has traced adverse allergic reactions in sensitized individuals to consumption of sandwiches and salads prepared by food handlers wearing latex gloves. *See* Personal Hygiene at 24-10.

C. Studies To Be Conducted

In addition to the foregoing information, FDA requested comments on areas that would be appropriate for further study. Given the potential for the use of gloves to discourage proper personal hygiene practices, we believe this is an area that would benefit from additional research. As discussed above, gloves alone will not serve as an effective barrier to the transmission of pathogens. Proper personal hygiene and sanitation practices are essential, regardless of whether food service personnel are wearing gloves. It would be helpful to have further data on the psychological effect of gloves on food service workers, *i.e.*, whether the presence of gloves creates an environment in which personal hygiene practices are more lax and, therefore, the risks of pathogen transmission are actually greater. In addition, and as a separate matter, it would be helpful to have further data on the difference in the efficacy of pathogen transmission from gloves to ready-to-eat foods and bare hands to ready-to-eat foods.

* * *

We appreciate the opportunity to provide you with the enclosed information and we hope you will find it useful. Please let us know if you have any questions regarding our submission or if we may be of assistance in any way.

Cordially yours,

Tim Hammonds
President and CEO

Enclosures

FOOD MARKETING INSTITUTE
800 CONNECTICUT AVE., N.W.
WASHINGTON, D.C. 20006-2701

Address Correction
Return Requested

Docket No. 99N-0438

Dockets Management Branch (HFA-305)

Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852